

PATENT
Customer No. 22,852
Attorney Docket No. 6832.0012



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
David J. BALLANCE et al.) Group Art Unit: 1653
Application No.: 09/832,501) Examiner: Hope A. Robinson
Filed: April 12, 2001)
For: ALBUMIN FUSION PROTEINS)
)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(c)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), applicants bring to the attention of the Examiner the documents listed on the two PTO 1449s attached (43 pages and 5 pages). This Information Disclosure Statement is being filed after the events recited in Section 1.97(b) but, to the undersigned's knowledge, before the mailing date of either a Final action, Quayle action, or a Notice of Allowance. Under the provisions of 37 C.F.R. § 1.97(c), this Information Disclosure Statement is accompanied by a fee of \$180.00 as specified by Section 1.17(p).

The Examiner indicated that copies of U.S. patent documents need not be provided. Copies of all other listed documents are attached.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

English translations of the following non-English patent documents are enclosed with the relevant documents:

JP 2 227079
JP 3 201987
WO 93/00437
WO 93/15200
WO 95/30759
WO 99/15193

English translations of the following non-English articles are also enclosed with the relevant documents:

Becquart, J., "Les Syncopes ou Malaises D'Origine Vasculaire," *Soins*, 504: 4-8 (1987).

Becquart J., et al., "Pronostic du Syndrome de Wolff-Parkinson-White chez le Nourrisson," *Arch. Mal. Coeur* 81:695-700 (1988).

Becquart, J., et al., "Insuffisance Aortique Argue Rhumatoide Traitee Par un Remplacement Valvulaire," *Arch. Mal. Coeur* 84:987-989 (1991).

Becquart, J., et al., "Les Pheochromocytomes Malins," *Annales De Cardiologie Et D'Andeliologie*, 36:191-196 (1987).

Cai, M. et al., "Development and Application of Hybridoma Secreting Monoclonal Antibody Against Poly-Human Serum Albumin" *J. WCUMS* 20(2):134-136 (1989).

Chen, Y-M., "Pulmonary Nocardiosis with Cerebral Abscess Successfully Treated by Medication Alone—A Case Report," *Chin. Med. J. (Taipei)* 47:294-298 (1991).

Chen, Y-M., et al., "Neurofibromatosis with Interstitial Pulmonary Fibrosis—Case Report and Literature Review," *Chin. Med. J. (Taipei)* 42:213-218 (1988).

Chen, Z., et al., "Enhancing the Immunogenicity of the preS Antigen of Hepatitis

B Virus by Genetically Fusing it with Interleukin-2," *Natl. Med. J. China* 76(1):34-37 (1996).

Dmitrenko, V.V., et al., "Heterogeneity of the Polyadenylation Site of mRNA Coding for Human Serum Albumin," *Genetika* 26(4):765-769 (1990).

Fedorchenko, S.V., et al., "Is it Possible to Overcome Resistance of Patients with Chronic Hepatitis B to Antiviral Therapy Because of Production of Antibodies to Recombinant α_2 -Interferon?" *Voprosy Virusologii* 5:218-220 (1994).

Hannebicque, G., et al., "Manifestations Cardiaques De La Maladie De Lyme," *Ann. Cardiol. Angelol.* 38:87-90 (1989).

Huang S-Z., et al., "A Study of Transgenic IFV Cattle with the Human Serum Albumin Gene Integrated," *ACTA Genetic Sinica* 27(7):573-579 (2000).

Hwang, G-S., et al., "Small Bowel Perforation Secondary to Metastatic Pulmonary Carcinoma," *Chin. Med. J. (Taipei)* 41(2):159-164 (1988).

Le Bras, M., et al., "Epidemiologie et Clinique des Maladies Tropicales D'importation," *La Revue de Medicine Interne* 13:205-210 (1992).

Matsuda, Y., et al., "Human Serum Albumin Variants," *Tanpakushitu Kakusan Koso* 33(5):930-935 (1988).

Ohtani, W., et al., "Structure of Recombinant Human Serum Albumin from *Pichia pastoris*," *J. Pharm. Soc. Japan* 117(4):220-232 (1997).

Ruzgas, T.A., et al., "Ellipsometric Study of Antigen-Antibody Interaction at the Interface Solid/Solution," *Biofizika*, 37 (1): 56-61 (1992).

Takeshima, K., et al., "Ligand Binding Properties and Esterase-like Activity of Recombinant Human Serum Albumin," *Regular Articles Yakugaku Zasshi* 116(8):622-629 (1996).

Thery, C., et al., "Filter Cave Temporaire Permettant le Diagnostic et la Fibrinolyse Chez les Patients Suspects d'embolie Pulmonaire Massive," *Arch. Mal. Coeur* 84:525-530 (1991).

Vincent, M.P., et al., "Surdosage a l'halofantrine," *La Presse Medicale* 3:131 (1992).

Yeh, P-F., et al., "Haemophilus Infection in Chronic Obstructive Pulmonary Disease Patients," *Chin. Med. J. (Taipei)*, 44:57-60 (1989).

Yeh, P-F., et al., "Tuberculosis Bacteremia," *China Med. J. (Taipei)* 47(4):290-293 (1991).

Zhong, S., et al., "Experimental Research on Inhibition of Hepatitis B Virus of Targeted Hepatocytes In Vitro by Antisense Oligonucleotides," *National Medical Journal of China* 75(7):392-395 (1995).

Zhou, C.S., et al., "A Monoclonal Antibody Directed Against an Enediyne Antitumor Antibiotic and its Preliminary Application," *ACTA Pharmaceutica Sinica* 32(1):28-32 (1997).

In lieu of English translations and as a concise statement of relevance of each, English language Derwent abstracts of the following non-English patent documents are enclosed with the following documents:

JP 1 117790
CN 1235981 A
CN 1239103 A
JP 2 117384
JP 3 27320
JP 4 211375
JP 5 292972
JP 6 38771
JP 6 22784
JP 8 53500
JP 8 59509
JP 8 51982

In lieu of a translation or statement of relevance, English-language patent equivalents and patent family information have been submitted for the following non-English patent documents:

EP 0 236 210 A1 (equivalent to U.S. Pat. Nos., 5,100,784 and 5,187,261)
EP 0 511 912 A1 (equivalent to U.S. Pat. No. 5,646,012)
EP 0 711 835 A1 (equivalent to U.S. Pat. No. 6,114,146)
FR 2,635,115 (equivalent to EP 0 361 991 A2)
FR 2,719,593 (equivalent to WO 95/30759, translated as above)
DE 37 23 781 A1 (equivalent to UK Pat. Application No. GB 2 193 631 A)
WO 93/15199 (equivalent to U.S. Pat. No. 5,876,969)
WO 93/15211 (equivalent to U.S. Pat. No. 5,665,863)

WO 96/14409 (equivalent to AU Pat. No. 704,594)
WO 96/14416 (equivalent to U.S. Pat. No. 6,149,911)

Finally, the following U.S. patent applications are already before the Examiner and have been considered. Therefore, the following applications are being cited to place them on record:

09/832,501	Ballance et al.	Filed 4/12/01
09/832,929	Rosen et al.	Filed 4/12/01
09/833,041	Rosen et al.	Filed 4/12/01
09/833,111	Rosen et al.	Filed 4/12/01
09/833,118	Rosen et al.	Filed 4/12/01

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute "prior art" under United States law, applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: March 4, 2004

By: Charles E Van Horn
Charles E. Van Horn
Reg. No. 40,266

INFORMATION DISCLOSURE CITATION

Atty. Docket No.	6832.0012	Appln. No.	09/832,501
Applicant	David J. Ballance et al.		
Filing Date	April 12, 2001	Group:	1653

U.S. PATENT DOCUMENTS

Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
OIP E 577 MAR 04 2004 PATENT & TRADEMARK OFFICE USA	4,456,748	6/26/84	Goeddel	536	27	
	4,530,901	7/23/85	Weissmann	435	70	
	4,569,908	2/11/86	Mark et al.	435	70	
	4,716,217	12/29/87	Caruthers et al.	530	351	
	4,734,491	3/29/88	Caruthers et al.	536	27	
	4,758,428	7/19/88	Mark et al.	424	85	
	4,966,843	10/30/90	McCormick et al.	435	69.51	
	5,002,764	3/26/91	Peets et al.	424	95.7	
	5,028,422	7/2/91	Tanner et al.	424	85.4	
	5,116,964	5/26/92	Capon et al.	536	23.5	
	5,128,126	7/7/92	Boniver	424	85.5	
	5,223,408	6/29/93	Goeddel et al.	435	69.3	
	5,256,410	10/26/93	Tanner et al.	424	85.7	
	5,272,070	12/21/93	Lehrman et al.	435	172.1	
	5,326,859	7/5/94	Sugano et al.	536	23.52	
	5,376,567	12/27/94	McCormick et al.	435	320.1	
	5,378,823	1/3/95	Martal et al.	536	23.52	
	5,480,640	1/2/96	Morales et al.	424	85.7	
	5,514,567	5/7/96	Sugano et al.	435	69.51	
	5,540,923	7/30/96	Ebbesen et al.	424	85.5	
	5,602,232	2/11/97	Reichert et al.	530	351	
	5,641,663	6/24/97	Garvin et al.	435	172.1	

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OIP MC	5,767,097	6/16/98	Tam	514	43	
MAR 04 2004 USPTO - TRADEMARK OFFICE	5,780,021	7/14/98	Sobel	424	85.4	
	5,795,779	8/18/98	McCormick et al.	435	360	
	6,063,772	5/16/00	Tam	514	43	
	6,069,133	5/30/00	Chiou et al.	514	44	
	6,150,337	11/21/00	Tam	514	43	
	6,172,046	1/9/01	Albrecht	514	43	
	6,299,872	10/9/01	Albrecht	424	85.7	
	6,387,365	5/14/02	Albrecht et al.	424	85.4	
	6,461,605	10/8/02	Cutler et al.	424	85.7	
	6,472,373	10/29/02	Albrecht	514	43	
	6,482,613	11/19/02	Goeddel et al.	435	69.51	
	6,514,500	2/4/03	Bridon et al.	424	193.1	
	6,610,830	8/26/03	Boeddel et al.	530	351	
	6,686,179	2/3/04	Fleer et al.	435	69.7	
	2004-01010134 A1		Rosen et al.			4/12/01
	2003-0104578 A1 (and pending claims)		Ballance			10/26/01
	10/702,536 (and pending claims)		Fleer et al.			11/7/03
	10/702,636 (and pending claims)		Fleer et al.			11/7/03

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O I P E S C T Y M A R 6 2 0 0 4 T R A D E M A R K O F F I C E	2003-0054554 A1		Becquart et al.			3/20/03 (publication date)
	2003-0082747 A1		Fleer et al.			5/1/03 (publication date)
	2003-0022308 A1		Fleer et al.			1/30/03 (publication date)
	2003-0036170 A1		Fleer et al.			2/20/03 (publication date)
	2003-0036171 A1		Fleer et al.			2/20/03 (publication date)
	2003-0036172 A1		Fleer et al.			2/20/03 (publication date)
	09/832,501		Ballance et al.			4/12/01
	09/832,929		Rosen et al.			4/12/01
	09/833,041		Rosen et al.			4/12/01
	09/833,111		Rosen et al.			4/12/01
	09/833,118		Rosen et al.			4/12/01

FOREIGN PATENT DOCUMENTS

	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
	0 032 134 A2	7/15/81	EPO			
	0 241 435 A2	10/14/87	EPO			
	0 300 466 B1	9/13/95	EPO			

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O I P E
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T R A D E M A R K O F F I C E

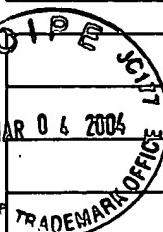
FOREIGN PATENT DOCUMENTS						
	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
	WO 83/02461	7/21/83	PCT			
	WO 92/01055	1/23/92	PCT			
	WO 94/19373	9/1/94	PCT			
	WO 99/66054	12/23/99	PCT			
	WO 02/46227	6/13/02	PCT			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
	Galliano M. et al., FEBS Letters 208:364-368 (1986).
	Galliano M. et al., FEBS Letters 233:100-104 (1988).
	Galliano M. et al., Proc. Natl. Acad. Sci. USA 87:8721-8725 (1990).
	Galliano M. et al., J. Biol. Chem. 261:4283-4287 (1986).
	Hershfield MS et al., Proc. Natl. Acad. Sci. USA 88:7185-7189 (1991).
	Minchiotti L et al., Biochimica et Biophysica Acta 1119:232-238 (1992).
	Peters T. Clin. Chem. 23:5-12 (1977).
	Reed, R.G., et al., Clin. Chem. 34:1992-1994 (1988).
	Weitkamp LR et al., Ann. Hum. Genet. 36:381-392 (1973).
	Weitkamp LR et al., Ann Hum Genet. 37:219-226 (1973).
	Interferon, alpha 2; Accession number NP_00596 (from NCBI GenBank) (Dec. 21, 2003)
	Similar to interferon, alpha 2; Accession number XP_011801 (from NCBI GenBank) (Oct. 16, 2001)
	Interferon, alpha 1; Accession number NP_076918 (from NCBI GenBank) (Dec. 20, 2003)
	IFNA2; Locus ID: 3440 (from NCBI LocusLink) (June 9, 1992)

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

MAR 04 2004	IFNA1; Locus ID: 3439 (from NCBI LocusLink) (June 2, 1986)
	USP Dictionary of USAN and International Drug Names; Interferon: CAS-9008-11-1 (2001)
	USP Dictionary of USAN and International Drug Names; Interferon Alfa: CAS-74899-72 (2001)
	USP Dictionary of USAN and International Drug Names; Interferon Alfa-2a: CAS-76543-88-9 (2001)
	USP Dictionary of USAN and International Drug Names; Interferon Alfa-2b: CAS-99210-65-8 (2001)
	USP Dictionary of USAN and International Drug Names; Interferon Alfacon-1: CAS-118390-30-0 (2001)

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OMB No. 0651-0011

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Filing Date	April 12, 2001	Group:	1653

U.S. PATENT DOCUMENTS

Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	4,336,248	06/22/82	Bonhard et al.	424	101	
	4,751,180	06/14/88	Cousens et al.	435	68	
	4,765,980	08/23/88	DePrince et al.	424	108	
	4,801,575	01/31/89	Pardridge et al.	514	4	
	4,914,027	04/03/90	Knapp et al.	435	69.6	
	4,959,314	09/25/90	Mark et al.	435	69.1	
	4,970,300	11/13/90	Fulton et al.	530	383	
	5,045,312	09/03/91	Aston et al.	424	85.8	
	5,073,627	12/17/91	Curtis et al.	530	351	
	5,100,784	03/31/92	Latta et al.	435	69.7	
	5,116,944	05/26/92	Sivam et al.	530	362	
	5,187,261	02/16/93	Latta et al.	530	363	
	5,302,697	04/12/94	Goodey et al.	530	325	
	5,330,971	07/19/94	Wells et al.	514	2	
	5,336,603	08/09/94	Capon et al.	435	69.7	
	5,380,712	01/10/95	Ballance et al.	514	12	
	5,612,196	03/18/97	Becquart et al.	435	69.6	
	5,646,012	07/08/97	Fleer et al.	435	69.1	
	5,665,863	09/09/97	Yeh et al.	530	351	
	5,679,777	10/21/97	Anderson et al.	530	385	
	5,705,363	01/06/98	Imakawa et al.	435	69.51	

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U.S. PATENT DOCUMENTS

Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	5,714,377	02/02/98	Tanner et al.	435	254.11	
	5,766,883	6/16/98	Ballance et al.	435	69.7	
	5,844,095	12/1/98	Linsley et al.	530	387.3	
	5,876,969	03/02/99	Fleer et al.	435	69.7	
	5,889,144	03/30/99	Alila et al.	530	300	
	5,948,428	09/07/99	Lee et al.	424	426	
	5,968,510	10/19/99	Linsley et al.	424	141.1	
	5,977,318	11/2/99	Linsley et al.	530	388.0	
	5,981,474	11/9/99	Manning et al.	514	2	
	6,114,146	09/05/00	Herlitschka et al.	435	69.7	
	6,149,911	11/21/00	Binz et al.	424	192.1	
	6,165,470	12/26/00	Becquart et al.	424	185.1	

FOREIGN PATENT DOCUMENTS

	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
	0 073 646 A2	03/09/83	EPO			
	0 079 739 A2	05/25/83	EPO			
	0 088 632 A2	09/14/83	EPO			
	0 091 527 A2	10/19/83	EPO			
	0 116 201 A1	08/22/84	EPO			

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	0 123 294 A1	10/31/84	EPO			
	0 123 544 A2	10/31/84	EPO			
	0 138 437 A2	04/24/85	EPO			
	0 147 198 A3	07/03/85	EPO			
	0 163 406 A1	12/04/85	EPO			
	0 196 056 B1	10/01/86	EPO			
	0 201 239 A1	11/12/86	EPO			
	0 206 733 A1	12/30/86	EPO			
	0 236 210 A1	09/09/87	EPO			English Equivalent
	0 244 221 A1	11/04/87	EPO			
	0 301 670 A1	02/01/89	EPO			
	0 308 381 A1	03/22/89	EPO			
	0 314 317 A1	05/03/89	EPO			
	0 319 641 A1	06/14/89	EPO			
	0 322 094 A1	06/28/89	EPO			
	0 325 262 A2	07/26/89	EPO			
	0 330 451 A2	08/30/89	EPO			
	0 344 459 A2	12/06/89	EPO			
	0 361 991 A2	04/04/90	EPO			
	0 364 980 B1	04/14/93	EPO			
	0 366 400 A2	05/02/90	EPO			

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	0 395 918 A2	11/07/90	EPO			
	0 399 666 B1	11/28/90	EPO			
	0 401 384 B1	3/13/96	EPO			
	0 413 622 B1	02/20/91	EPO			
	0 416 673 A1	03/13/91	EPO			
	0 503 583 A1	09/16/92	EPO			
	0 509 841 A2	10/21/92	EPO			
	0 510 678 A2	10/28/92	EPO			
	0 510 693 A2	10/28/92	EPO			
	0 511 912 A1	11/4/92	EPO			English Equivalent
	0 711 835 A1	05/15/96	EPO			English Equivalent
	0 771 871 A2	07/5/97	EPO			
	1 117790	05/10/89	Japan			Abstract
	1235981A	11/24/99	China			Abstract
	1239103A	12/22/99	China			Abstract
	2 117384	05/01/90	Japan			Abstract
	2 193 631 A	02/17/88	UK			
	2 227079	09/10/90	Japan			Yes
	2 350 362 A	11/29/00	UK			
	2 635 115	09/06/90	France			English Equivalent
	2 719 593	11/10/95	France			English Equivalent

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	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
	2022539	02/04/91	Canada			
	3 201987	09/03/91	Japan			Yes
	3 27320	02/5/91	Japan			Abstract
	37 23 781 A1	01/21/88	Germany			English Equivalent
	4 211375	08/03/92	Japan			Abstract
	5 292972	11/09/93	Japan			Abstract
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	WO 93/15199	08/5/93	PCT			English Equivalent
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